

## Claims

1. An anastomosis device comprising  
a hollow, elongate, flexible catheter body having a proximal end and a  
distal end,  
5 an inflatable balloon at the distal end,  
a drainage lumen connected to the distal end, and  
tissue approximating structure on the catheter body on a proximal side of  
the balloon at a location to contact severed tissue during an anastomosis procedure.
- 10 2. The device of claim 1 wherein, when the device is installed in a body having a  
prostate removed, with the balloon in a bladder, the tissue approximating structure is  
capable of contacting tissue selected from tissue of a bladder, tissue of a perineal wall,  
urethral tissue, and combinations of these.
- 15 3. The device of claim 1 wherein the tissue approximating structure comprises  
movable elongate structure selected from a tine, a probe, a prod, and a needle.
4. The device of claim 3 wherein the tissue approximating structure can be extended  
and retracted from apertures in the catheter body using an actuating mechanism that  
20 extends through a lumen along a portion of the length of the device to the proximal end.
5. The device of claim 1 comprising  
a hollow, elongate, flexible catheter body having a proximal end and a  
distal end,  
25 an inflatable balloon at the distal end and an inflation lumen extending  
from the proximal end to the balloon,  
a drainage lumen extending from a drainage aperture at the distal end to a  
port at the proximal end, and  
movable elongate tissue approximating structure positioned to extend  
30 through apertures in the hollow catheter body at the distal end.

6. The device of claim 1 comprising  
a hollow, elongate, flexible catheter body having a proximal end and a  
distal end,  
an inflatable balloon at the distal end and an inflation lumen extending  
5 from the proximal end to the balloon,  
a drainage lumen extending from a drainage aperture at the distal end to a  
drainage port at the proximal end, and  
distal tissue approximating structure comprising movable elongate tines  
positioned to extend through apertures in the hollow catheter body on the proximal side  
10 of the balloon, and  
proximal tissue approximating structure comprising movable elongate  
tines positioned to extend through apertures in the hollow catheter body on the proximal  
side of the distal tissue approximating structure.
- 15 7. The device of claim 1 wherein the tissue approximating structure comprises  
multiple tines.
8. The device of claim 1 wherein the tissue approximating structure comprises  
multiple opposing tines.
- 20 9. An anastomosis device comprising  
a hollow elongate flexible catheter body having a proximal end and a  
distal end,  
an inflatable balloon at the distal end and inflation means to inflate the  
25 balloon,  
drainage means connected to the distal end for draining urine from a  
bladder, and  
tissue approximating means on the catheter body on the proximal side of  
the balloon for holding severed tissue in contact for healing.
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10. The device of claim 9 wherein the tissue approximating means are located on the distal end.
11. The device of claim 9 further comprising actuating means for actuating the tissue approximating means, the actuating means connected to the tissue approximating means and extending from the tissue approximating means to the proximal end.
12. The device of claim 9 wherein the tissue approximating structure is selected from the group consisting of an inflatable balloon, a movable elongate structure, and a combination thereof.
13. The device of claim 9 wherein the tissue approximating structure comprises a movable tine.
14. The device of claim 9 wherein, with the device positioned to place the at least a portion of the catheter body inside the urethra and the inflated balloon in the bladder, the tine can be extended to contact tissue selected from the group consisting of bladder tissue, urethral tissue, urethral stump tissue, and perineal wall tissue.
15. A method of performing urethral anastomosis, the method comprising  
inserting a portion of an anastomosis device into the urethra, the anastomosis device comprising  
tissue approximating structure and  
a distal end comprising a balloon,  
inflating the balloon in the bladder, and  
using the tissue approximating structure to hold severed tissue together.
16. The method of claim 15 comprising vesico-urethral anastomosis, the method comprising  
removing a prostate to leave a urethral stump and a bladder neck on a bladder,

- inserting a portion of an anastomosis device through the urethral stump  
and through the bladder neck into the bladder, the anastomosis device comprising  
tissue approximating structure and  
a distal end comprising a balloon,  
5 inflating the balloon inside the bladder,  
moving the bladder neck to contact the urethral stump, and  
using the tissue approximating structure to hold the urethral stump against  
the bladder neck to allow healing of the urethral stump to the bladder neck.
- 10 17. The method of claim 16 comprising using the tissue approximating structure to  
hold the urethral stump in contact with the bladder neck for a time sufficient to allow the  
urethral stump and the bladder neck to heal together.
- 15 18. The method of claim 15 comprising end-to-end urethral anastomosis, the method  
comprising  
severing a urethra to produce two opposing severed urethral portions,  
inserting a portion of an anastomosis device into the urethra, the  
anastomosis device comprising  
tissue approximating structure and  
20 a distal end comprising a balloon,  
inflating the balloon in the bladder,  
moving the two opposing severed urethral portions into contact, and  
using the tissue approximating structure to hold the two opposing severed  
urethral portions in contact to allow the tissue portions to heal together.
- 25 19. The method of claim 18 comprising using the tissue approximating structure to  
hold the opposing severed urethral portions together for a time sufficient to allow the  
severed urethral portions to heal together.
- 30 20. The method of claim 15 wherein the tissue approximating structure comprises  
multiple tines.

21. A method of performing a urethral anastomosis, the method comprising  
severing a urethra to leave opposing severed urethral tissues,  
inserting a distal end of an anastomosis device through the urethra and into  
5 the bladder, the anastomosis device comprising  
tissue approximating structure and  
a balloon,  
inflating the balloon inside of the bladder,  
holding the opposing severed urethral tissues together in healing contact  
10 using the tissue approximating structure.
22. The method of claim 21 comprising performing a radical prostatectomy, the  
method comprising  
removing a prostate to leave a urethral stump and a bladder neck,  
15 inserting an anastomosis device through the urethral stump and through  
the bladder neck, the anastomosis device comprising a balloon and tissue approximating  
structure,  
inflating the balloon inside of the bladder,  
holding the urethral stump and the bladder neck together in healing  
20 contact using the tissue approximating structure.
23. The method of claim 22 wherein the anastomosis device remains in place for a  
time to effect healing of the urethra stump to the bladder neck.
- 25 24. The method of claim 21 comprising filling the bladder using a drainage port on  
the distal end and checking for leaks at the anastomosis site.
25. The method of claim 22 wherein the urethral anastomosis is an end-to-end  
urethral anastomosis comprising severing the urethra below a perineal wall and re-  
30 connecting the severed tissue.